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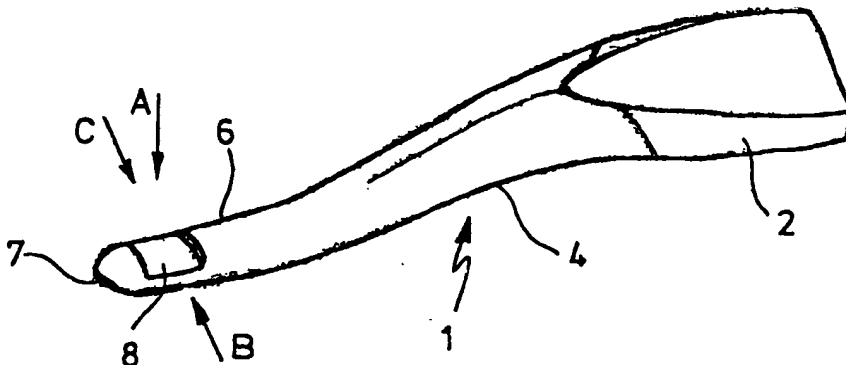
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SURGICAL AUXILIARY INSTRUMENT



(57) Abstract: A surgical auxiliary instrument (1) contains a grip section (2) in the proximal region, an adjoining intermediate section (4) and, in the distal region, an application section (6) set up for laying against an implant tape. The application section (6) is preferably provided with a depression (8).

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Surgical auxiliary instrument

The invention relates to a surgical auxiliary instrument which can be used in particular in so-called TVT procedures.

The TVT surgical technique is a procedure for treating female
5 incontinence as described e.g. in WO 96/06567 and WO 97/13465.
A surgical instrument is used in which a strong bent surgical
needle, which is guided with the help of a removable grip, is
secured to each end of an implant tape made of polypropylene.
The two needles are guided on opposite sides of the patient's
10 urethra via the vagina along the rear side of the pubic bone to
the outside of the abdominal wall. The tape comes to rest in a
curve below the urethra. The two ends of the tape are pulled
through the abdominal wall and cut off. As a rule, they need not
be sewn as the tape grows in in the tissue relatively quickly.
15 In the region of the urethra, the tape acts as a support without
touching the urethra directly. The procedure is facilitated if
the tape is provided with two covers which increase the gliding
properties in the tissue and are removed from the tape at the
end of the procedure via the two exit points of the tape. With
20 this method, urinary incontinence can be treated quickly, effec-
tively and in a manner causing little stress.

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A correct position of the tape below the urethra is important. The tape must sit neither too tautly nor too slack. If the covers mentioned are removed from the tape towards the end of the procedure, there is a risk that the tape ends are taken along
5 for a little with them and thus the tape below the urethra becomes too short and too taut. As a rule, the surgeon prevents this by inserting closed scissors between urethra and tape, with which he holds back the tape. In this manner he can also correct the position of the tape with the scissors in other phases of
10 the procedure.

However, scissors are not a particularly suitable instrument for the named purpose. Handling is awkward and can even lead to injuries.

15 The object of the invention is to provide a possibility to facilitate the course of a procedure in which a tape is inserted, in particular a TVT procedure.

20 This object is achieved by a surgical auxiliary instrument with the features of claim 1. Advantageous designs of the invention result from the dependent claims. Claims 8 and 9 relate to the appropriate preparation of such a surgical auxiliary instrument for a TVT procedure.

25 The surgical auxiliary instrument according to the invention has a gripping section in the proximal zone, an adjoining intermediate section and an application section in the distal region set up for laying against an implant tape. If it is used during
30 a TVT procedure, the application section is inserted between the patient's urethra and the pulled-in implant tape. Through the exertion of force, directed away from the urethra, on the auxiliary instrument, the position of the implant tape can be set, corrected or retained.

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As the application section is set up for laying against the implant tape, the auxiliary instrument is much more suitable than scissors for checking the position of the tape below the urethra and ensuring a correct position. Thus the tape can be held with the auxiliary instrument when the covers are removed from the tape ends. Furthermore, it is possible to set and correct the position of the tape below the urethra and thus to prevent the tape tension from becoming too great and the tape from sitting too tautly. In principle, the auxiliary instrument according to the invention is used in similar manner to the aforementioned scissors, but because of its design, it is much more suitable for the purpose for which it is intended. In particular, injuries can be avoided by atraumatic shaping.

15 The application section preferably runs cranked relative to the grip section. This means that the intermediate section extends essentially at an obtuse angle relative to the grip section and the application section at a similar angle to the intermediate section, so that the grip section and the application section run largely parallel, but are offset relative to each other. This design is particularly suitable for use in a TVT procedure, as it makes possible a comfortable handling of the auxiliary instrument.

25 In a preferred version of the auxiliary instrument, the application section contains a depression, the length of which, measured in longitudinal direction of the auxiliary instrument, is at least as great as the width of the implant tape to be used. This depression is open at both longitudinal sides of the auxiliary instrument. When the application section is inserted between the patient's urethra and the implant tape, the implant tape comes to rest in the depression and runs transversely with respect to the auxiliary instrument. The depression prevents the auxiliary instrument from slipping from the implant tape and thus increases reliability. When the application section runs cranked relative to the grip section, the depression is preferably accessi-

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ble from the side on which the grip section is located. In this case, the advantages of the depression for a secure guiding of the implant tape and the cranked basic shape of the auxiliary instrument for a favourable position of the grip section come
5 into play.

There are many possibilities for the design of the surgical auxiliary instrument according to the invention. The application section is preferably designed flat. The intermediate section
10 can have a reinforcing profile which can also continue into the grip section. The auxiliary instrument is preferably manufactured from plastic as an injection moulding. In another version, it is bent into shape from a sheet metal part.

15 In the following, the invention is described in more detail using embodiments. The drawings show in

Figure 1 a perspective view of a first version of the surgical auxiliary instrument according to the invention,
20

Figure 2 a side view of the version from Figure 1, the cross-sectional shape of the auxiliary instrument at each of the points indicated by the dash-dot lines being given in the lower region of Figure 2,
25

Figure 3 a perspective view of a second version of the surgical auxiliary instrument according to the invention and

Figure 4 a perspective view of the version from Figure 3 as
30 seen from a different angle.

A first version of a surgical auxiliary instrument 1 is shown in Figures 1 and 2. The auxiliary instrument 1 contains in its proximal region a grip section 2 and adjoining it an intermediate
35 te section 4, which is provided with a profile 5 serving to reinforce it, which continues into the grip section 2. The di-

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stal region of the auxiliary instrument 1 is formed as an application section 6 and set up for laying against an implant tape. The distal end 7 of the auxiliary instrument 1 is rounded. Overall, the shape is atraumatic.

5

As can be seen in particular in Figure 2, the application section 6 runs cranked relative to the grip section 2. The application section 6 and the grip section 2 are therefore aligned largely parallel to each other but, because the intermediate
10 section 4 extends at a slope, are offset relative to each other.

A depression 8 is formed in the application section 6. The length of the depression 8, measured in longitudinal direction of the auxiliary instrument 1, is somewhat greater than the
15 width of an implant tape, the position of which can be set or corrected with the auxiliary instrument 1. The depression 8 starts from the side on which the grip section 2 is located, i.e. the top according to the representations in Figures 1 and 2. The depression 8 is therefore accessible from this side, i.e.
20 in the direction of the arrow A. The depression 8 is open on the two longitudinal sides of the auxiliary instrument 1; it is therefore also accessible in the directions identified by arrows B and C. This design of the depression 8 makes it possible to accomodate the implant tape in the depression 8 when it runs
25 transversely with respect to the auxiliary instrument 1, so that it rests securely against the application section 6 and cannot slip off.

The auxiliary instrument 1 is manufactured from plastic as an
30 injection moulding and can be in one piece or several pieces. In the embodiment, it is in two pieces, the grip section 2 being inserted into the intermediate section 4.

Figures 3 and 4 show two perspective views of a second version
35 of the auxiliary instrument, here numbered 11, as seen from different angles.

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The auxiliary instrument 11 contains a grip section 12, an intermediate section 14 and an application section 16 with a distal end 17 and a depression 18. In their function, these parts correspond to the parts explained using Figures 1 and 2. The application section 16 again runs cranked relative to the grip section 12. In contrast to the auxiliary instrument 1, the auxiliary instrument 11 is shaped from a piece of sheet metal.

The surgical auxiliary instrument is suitable in particular for use in a TVT procedure, as explained in the following using the auxiliary instrument 1. The surgical technique itself is summarized at the beginning and described in more detail in the documents cited there. When the implant tape has been pulled in and lies below the patient's urethra, the surgeon must check and if necessary correct the position of the tape. To this end, he pushes the auxiliary instrument 1 between the urethra and the tape so that the tape comes to rest in the depression 8 and runs transversely with respect to the auxiliary instrument 1. Through pressure onto the grip section 2, he can increase the distance between the urethra and the tape, in order to thus optimally set or correct the position of the tape. If, towards the end of the procedure, the covers mentioned at the beginning are pulled off from the ends of the implant tape, the surgeon can, with the auxiliary instrument 1, prevent the tape from being taken along and consequently lying too tightly against the urethra.

The cranked shape of the auxiliary instrument 1 is geared to use in a TVT procedure. It enables the application section 6 to be located in the desired operating area whilst the grip section 2 lies outside and can be gripped without difficulty.

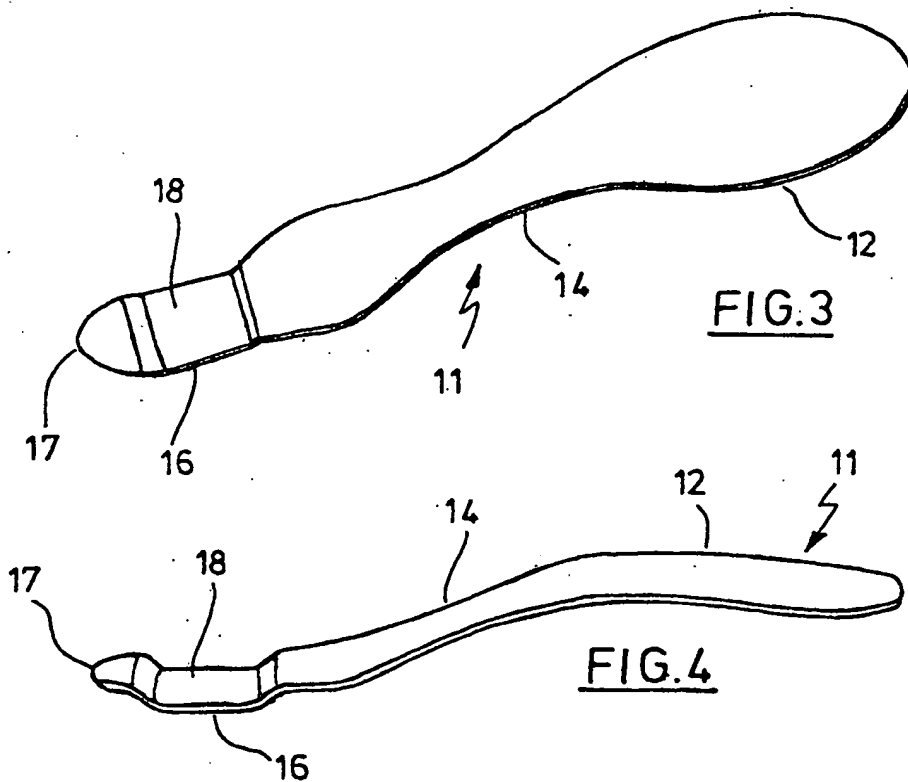
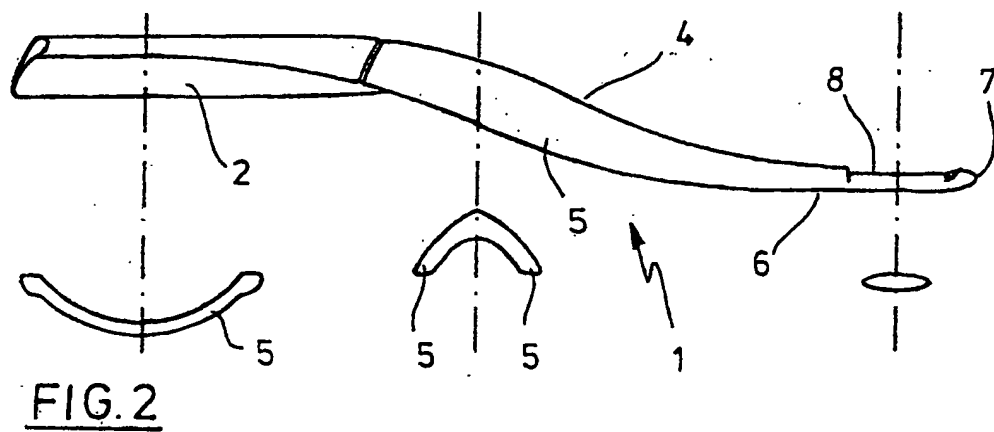
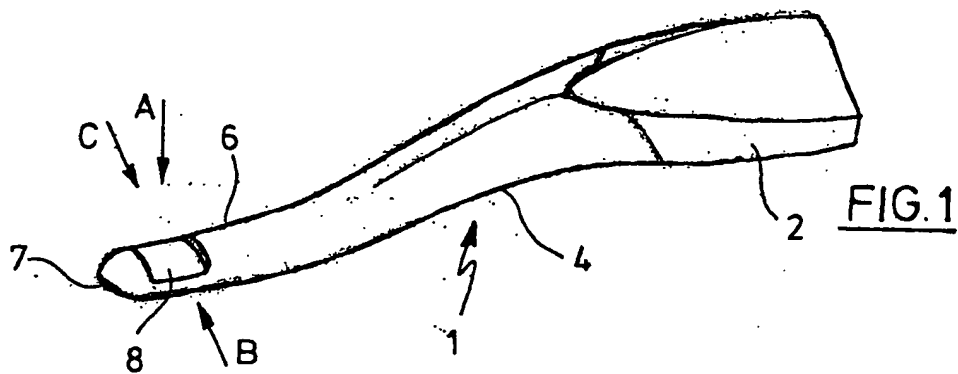
- 7 -

Claims

1. Surgical auxiliary instrument with a grip section (2; 12) in the proximal region, an adjoining intermediate section (4; 14) and an application section (6; 16), in the distal region, set up for laying against an implant tape.
5
2. Surgical auxiliary instrument according to claim 1, characterized in that the application section (6; 16) runs cranked relative to the grip section (2; 12).
- 10 3. Surgical auxiliary instrument according to claim 1 or 2, characterized in that the application section (6; 16) has a depression (8; 18), the length of which, measured in longitudinal direction of the auxiliary instrument (1; 11), is at least as great as the width of the implant tape to be
15 used, and which is open on both longitudinal sides of the auxiliary instrument (1; 11).
4. Surgical auxiliary instrument according to claim 2 and
20 claim 3, characterized in that the depression (8; 18) is accessible from the side on which the grip section (2; 12) is located.
5. Surgical auxiliary instrument according to one of claims 1
25 to 4, characterized in that the application section (6; 16) is designed flat.
6. Surgical auxiliary instrument according to one of claims 1
30 to 5, characterized in that the intermediate section (4) has a reinforcement profile (5).
7. Surgical auxiliary instrument according to one of claims 1 to 6, characterized in that it is designed as an injection moulding (1).

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8. Use of a surgical auxiliary instrument according to one of claims 1 to 7 in a TVT procedure, in which the application section (6; 16) is pushed between the patient's urethra and the pulled-in implant tape, and the position of the implant tape is checked, set, corrected or maintained through an exertion of force, directed away from the urethra, on the auxiliary instrument (1; 11).
9. Use according to claim 8, in which the auxiliary instrument has the features of claim 3, characterized in that the implant tape comes to rest in the depression (8; 18) and runs transversely with respect to the auxiliary instrument (1; 11).



INTERNATIONAL SEARCH REPORT

International Application No.

PCT/EP 02/12849

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/04 A61B17/42 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 820 187 A (COUTURE RAYMOND) 5 November 1937 (1937-11-05) page 1, line 31 - line 42; figures 1,2 ---	1-3,6
A	US 3 776 240 A (WOODSON E) 4 December 1973 (1973-12-04) column 2, line 24 - line 61; figures 1-5 ---	1,2
A	WO 97 13465 A (MEDSCAND MEDICAL AB ;ULMSTEN ULF (SE)) 17 April 1997 (1997-04-17) abstract; figure 1 -----	1



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

A document member of the same patent family

Date of the actual completion of the international search

17 February 2003

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26/02/2003

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 02/12849

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 8, 9
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 02/12849

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